General

Guideline Title

The official positions of the International Society for Clinical Densitometry: vertebral fracture assessment.

Bibliographic Source(s)

Rosen HN, Vokes TJ, Malabanan AO, Deal CL, Alele JD, Olenginski TP, Schousboe JT. The official positions of the International Society for Clinical Densitometry: vertebral fracture assessment. J Clin Densitom. 2013 Oct-Dec;16(4):482-8. [25 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Schousboe JT, Vokes T, Broy SB, Ferrar L, McKiernan F, Roux C, Binkley N. Vertebral fracture assessment: the 2007 ISCD official positions. J Clin Densitom. 2008 Jan-Mar;11(1):92-108.

Recommendations

Major Recommendations

The definitions for quality of evidence (Good, Fair, Poor), strength of recommendations (A–C), and application of recommendations (W, L) are provided at the end of the "Major Recommendations" field.

What Are the Appropriate Indications for Vertebral Fracture Assessment (VFA)?

2013 International Society for Clinical Densitometry (ISCD) Official Position

Lateral spine imaging with standard radiography or densitometric VFA is indicated when T-score is less than -1.0 and of one or more of the following is present:

a. Women age ≥70 yr or men age ≥80 yr
b. Historical height loss >4 cm (>1.5 inches)
c. Self-reported but undocumented prior vertebral fracture
d. Glucocorticoid therapy equivalent to ≥5 mg of prednisone or equivalent per day for ≥3 mo
   Grade: Fair-B-W

Definitions:

Quality of Evidence

Good: Evidence includes consistent results from well-designed, well-conducted studies in representative populations.

Fair: Evidence is sufficient to determine effects on outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies.

Poor: Evidence is insufficient to assess the effects on outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information.

Strength of Recommendations

A: Strong recommendation supported by the evidence

B: Recommendation supported by the evidence

C: Recommendation supported primarily by expert opinion

Application of Recommendations

W: Worldwide recommendation

L: Application of recommendation may vary according to local requirements

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Osteoporosis
- Osteopenia
- Vertebral fractures

Guideline Category

Diagnosis

Evaluation

Risk Assessment

Technology Assessment

Clinical Specialty

Endocrinology

Family Practice

Geriatrics

Internal Medicine

Obstetrics and Gynecology

Radiology

Rheumatology

Intended Users

Physicians

Guideline Objective(s)

- To revisit the indications for vertebral fracture assessment (VFA), review the literature published since the 2007 Position Development Conference, and to use heretofore unpublished cohort data to develop evidence-based indications for VFA
- To outline an update of the 2007 International Society for Clinical Densitometry Official Positions regarding VFA, presenting a critical appraisal of the following issues regarding VFA: the appropriate indications for VFA for post-menopausal women younger than age 65 and men younger than age 70

Target Population

Patients with, or at risk for, vertebral fracture

Interventions and Practices Considered

1. Lateral spine imaging with standard radiography or densitometric vertebral fracture assessment (VFA)
2. Risk assessment for VFA based on T-score, age, historical height loss, self-reported prior vertebral fracture, glucocorticoid use

Major Outcomes Considered

- Vertebral fracture prevalence
- Association of predictors with prevalent vertebral fracture
- Sensitivity and specificity of indications used in prediction models

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Task Force members performed a medical literature search relevant to the clinical and/or technical questions using a method modified from that utilized by the Cochrane reviews. The literature searches were conducted using electronic databases that included PubMed and MEDLINE, for the period 1/1/2007 through 2/28/2013. Appropriate articles were selected from the searches for further review, and combined with the articles for the time period prior to 1/1/2007 that had been identified by the 2007 Vertebral Fracture Assessment Task Force.

Number of Source Documents

251 (since 1/1/2007)

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence

Good: Evidence includes consistent results from well-designed, well-conducted studies in representative populations.

Fair: Evidence is sufficient to determine effects on outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies.

Poor: Evidence is insufficient to assess the effects on outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

The development of the International Society for Clinical Densitometry (ISCD) Official Positions was undertaken according to the RAND/University of California, Los Angeles (UCLA) Appropriateness Method (RAM). This is a mechanism to determine whether procedures or indications are expected to provide a specific health benefit, designated as "appropriate," that exceeds the potential negative consequences by such a wide margin that the procedure or indication is worth doing, exclusive of cost. The rationale for use of the RAM for the Position Development Conference is based on its ability to combine the best available scientific evidence with the collective judgment of worldwide experts in the bone field, to yield appropriate recommendations that are patient- and technology-specific.

Methods Used to Formulate the Recommendations

Expert Consensus (Consensus Development Conference)

Description of Methods Used to Formulate the Recommendations

Position Development Conference (PDC) Expert Panel

Concurrent with Task Force work, international experts in the field of bone densitometry and societies specific to skeletal health were contacted by the PDC Steering Committee to serve as member panelists. Twelve experts agreed to participate on the PDC Expert Panel. In addition to individuals representing many regions of the world, one official representative from each of the following professional societies were participants on the expert panel: The American Society for Bone and Mineral Research (ASBMR), the North American Menopause Society (NAMS), and the National Osteoporosis Foundation (NOF). The role of the Expert Panel was to review the proposed Official Positions and supportive documents developed by the task forces and make final recommendations to the International Society for Clinical Densitometry Board of Directors (ISCD BOD).

PDC Moderators

PDC panel Moderators with experience in the RAND/University of California, Los Angeles (UCLA) Appropriateness Method (RAM) were selected by the Steering Committee. Two moderators assisted the Chair of the PDC in the development and refinement of statements derived from the initial Task Forces questions and sub-questions and, along with the Chair of the PDC, lead the discussion and the rating by the Expert Panel during the PDC in Tampa, Florida, USA.

Grading of the Official Positions

All Official Positions for the 2013 PDC were rated by the Expert Panel in the following categories: appropriateness, necessity, quality of evidence,

strength of recommendations and application of recommendations (see the "Rating Scheme for the Strength of the Evidence" and the "Rating Scheme for the Strength of the Recommendations" fields).

Proposed ratings in all cases, except the RAM ratings for appropriateness and necessity for each of the above categories, were included in the preliminary Official Positions crafted by each Task Force. Final ratings were determined by the on site meeting, convened Expert Panel that included appropriateness and necessity.

A rating of "appropriate" was required in order for a statement to be sent to the BOD for selection as an ISCD Official Position. Ratings of each Official Position from the 2013 PDC are expressed in the form of four characters representing quality of the evidence, strength of the recommendation, application of the recommendation, and whether it is necessary as previously described. For example, a rating "Good-A-W-Necessary" indicates that the evidence includes consistent results from well-designed, well-conducted studies in representative populations, a strong recommendation supported by the evidence, worldwide recommendation, and is necessary to perform in all instances. Since PDC topics are often selected because strong medical evidence is unavailable, it is the nature of the process that Official Positions are not always supported by the highest possible level of evidence. Nevertheless, the ISCD Official Positions encourage consistent approaches in the clinical practice of bone densitometry, and focus attention on issues that require further study.

PDC Procedures

After the initial selection of topics by the Board of Directors and Scientific Advisory Committee, the PDC Steering Committee selected three Task Force chairpersons, one for each of the three major PDC topics. Thereafter, the PDC Steering Committee and Task Force chairpersons worked collectively to select international experts as members of their respective Task Forces with the knowledge required to evaluate their assigned PDC topic. All topic questions and sub-questions that were generated by each Task Force were thoroughly researched in the scientific medical literature.

Prior to the PDC meeting in Tampa, Florida, USA, topic questions and sub-questions were converted into recommendation statements that were sent to the Expert Panel for an initial "appropriateness" rating. The PDC required a median "appropriateness" rating in either the upper third or lower third of the rating continuum (continuum was 1 to 9 with clusters 7 to 9 representing the upper third and clusters 1 to 3 representing the lower third) without "disagreement." "Disagreement" was defined as lack of consensus being predetermined to be four or more Expert Panelists rating in extreme clusters 1 to 3 and 7 to 9. In circumstances where the median "appropriateness" rating was less than 7, no Official Position was developed.

In making its decisions, the Expert Panel considered the level of the medical evidence, expert opinion, and the clinical need for a recommendation. In some instances, regulatory issues received consideration. The statements rated as "appropriate" with a median score of 7 or higher without "disagreement" by the Expert Panel were designated Official Positions. The statements rated as "uncertain" with a median score between four and six or any median score with "disagreement" were further discussed at the PDC. After the initial rating the documents supporting all Task Forces' recommendations were sent to the Expert Panelists for review. In brief, Task Force chairs presented reports on their topics supporting the "uncertain" statements to the Expert Panelists in closed session on the first day of the conference. These statements were then edited by Task Force chairs, if necessary, reflecting suggestions made by the Expert Panelists. Re-rating of "uncertain" statements occurred during each Task Force chairpersons' presentation when the PDC Moderators felt there was a significant likelihood of change in the opinions of the Expert Panel.

After all statements rated as "appropriate without disagreement" had been selected and all supporting evidence presented, the Expert Panel performed a final rating for necessity, quality of the evidence, strength of the recommendation, and application of the recommendation. The proposed Official Positions with supportive evidence were presented by the Task Force chairs at a meeting open to the public (in conjunction with the ISCD Annual Meeting) and attended by ISCD members, representatives from companies with interests in bone health and skeletal assessment, and other individuals with interest in bone disease and densitometry. All participants were encouraged to provide comments and suggestions to the expert panelists. On the next day, the Expert Panelists, in closed session, determined final wording of the proposed Official Positions.

Rating Scheme for the Strength of the Recommendations

All Official Positions for the 2013 Position Development Conference were rated by the Expert Panel in the following categories:

Appropriateness: Statements that the Expert Panel rated as "appropriate without disagreement" according to predefined criteria derived from the RAND/University of California, Los Angeles (UCLA) Appropriateness Method (RAM) were referred to the International Society for Clinical Densitometry Board of Directors (ISCD BOD) with a recommendation to become ISCD Official Positions. A statement was defined as "appropriate" when the expected health benefit exceeded the expected negative consequences by a significant margin such that it was worth performing.

Necessity: Recommended Official Positions that were rated by the Expert Panel were then rated according to necessity to perform in all circumstances, i.e., whether the health benefits outweighed the risks to such an extent that it must be offered to all patients. Necessity rating was conducted in a similar fashion as the appropriateness rating, in that each Official Position had to be rated as necessary without disagreement using similar predefined RAM criteria.

Strength of Recommendations

A: Strong recommendation supported by the evidence

B: Recommendation supported by the evidence

C: Recommendation supported primarily by expert opinion

Application of Recommendations

W: Worldwide recommendation

L: Application of recommendation may vary according to local requirements

Cost Analysis

For the reduction of incident vertebral fractures alone from drug therapy, a strategy of vertebral fracture assessment (VFA) for this population followed by selective radiography for those with apparent mild or moderate deformities on VFA is cost-effective for U.S. Caucasian women age 60 and older. Cost-effectiveness studies have suggested that the incremental gains of fracture reduction with initial teriparatide therapy compared to an anti-resorptive agent may be achieved cost-effectively in those with the worst bone mineral density (BMD) (T-scores <-4.0) if they also have a prevalent vertebral fracture. When bisphosphonates cannot be tolerated or are contraindicated, teriparatide may be cost-effective in women with osteoporosis by BMD criteria compared to no drug therapy, but only in those with a prevalent vertebral fracture. Teriparatide may be particularly cost-effective in these instances if there has been a recent vertebral fracture.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

The proposed Official Positions with supportive evidence were presented by the Task Force chairs at a meeting open to the public and attended by International Society for Clinical Densitometry (ISCD) members, representatives from companies with interests in bone health and skeletal assessment, and other individuals with interest in bone disease and densitometry. All participants were encouraged to provide comments and suggestions to the expert panelists. On the final day, the Expert Panelists, in closed session, determined final wording of the proposed Official Positions.

Following completion of the Position Development Conference, the Steering Committee finalized recommendation wording without changing content. These recommendations were then presented to the International Society for Clinical Densitometry Board of Directors (ISCD BOD) for review and voting. The BOD did not alter the content or wording of the proposed Official Positions. Recommendations approved by a majority vote of the ISCD BOD became ISCD Official Positions.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is specifically stated for each recommendation (see the "Major Recommendations" field).

Since the field of bone densitometry is new and evolving, some clinically important issues that are addressed at the Position Development Conferences are not associated with robust medical evidence. Accordingly some Official Positions are based largely on expert opinion.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Appropriate assessment and detection of vertebral fractures
- Appropriate reporting of vertebral fracture assessments

Potential Harms

Small amount of radiation exposure

Qualifying Statements

Qualifying Statements

Since Position Development Conference topics are often selected because strong medical evidence is unavailable, it is the nature of the process that Official Positions are not always supported by the highest possible level of evidence. Nevertheless, the International Society for Clinical Densitometry (ISCD) Official Positions encourage consistent approaches in the clinical practice of bone densitometry, and focus attention on issues that require further study.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy included publication of the International Society for Clinical Densitometry (ISCD) Official Positions in international journals that directly or indirectly pertain to skeletal diseases and the measurement of skeletal health.

Formal presentation of the ISCD Official Positions occurs at ISCD Annual Scientific Meetings, all ISCD Adult and Pediatric Bone Density Educational Courses, and ISCD Vertebral Fracture Assessment Educational courses. The Official Positions have been published in the society's official journal, Journal of Clinical Densitometry and Assessment of Skeletal Health.

Implementation Tools

Foreign Language Translations

Quick Reference Guides/Physician Guides

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Identifying Information and Availability

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2008 Mar (revised 2013 Oct-Dec)

Guideline Developer(s)

International Society for Clinical Densitometry - Nonprofit Organization

Source(s) of Funding

International Society for Clinical Densitometry

Guideline Committee

2013 Vertebral Fracture Assessment Task Force

Composition of Group That Authored the Guideline

Task Force Members: Harold N. Rosen, MD, CCD (*Chair*), Division of Endocrinology, Department of Medicine, Beth Israel Deaconess Medical Center, Boston, MA, USA; Tamara J. Vokes, MD, CCD, Division of Endocrinology, Department of Medicine, University of Chicago, Chicago, IL, USA; Alan O. Malabanan, MD, CCD, Division of Endocrinology, Department of Medicine, Beth Israel Deaconess Medical Center, Boston, MA, USA; Chad L. Deal, MD, CCD, Department of Rheumatology, Orthopedic and Rheumatology Institute, Cleveland, OH, USA; Jimmy D. Alele, MD, CCD, Division of Endocrinology, Department of Medicine, St Rita Hospital, Lima, OH, USA; Thomas P. Olenginski, MD, FACP, Division of Rheumatology, Department of Medicine, Geisinger Medical Center, Danville, PA, USA; John T. Schousboe, MD, PhD, CCD, Park Nicollet Institute for Research and Education and University of Minnesota, Minneapolis, MN, USA

Financial Disclosures/Conflicts of Interest

None disclosed

Guideline Status

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Guideline Availability

Electronic copies: Available to subscribers from the Journal of Clinical Densitometry Web site.

Print copies: Available from the International Society for Clinical Densitometry, 342 North Main St., West Hartford, CT 06117-2507; Phone: (860) 586-7563; Fax: (860) 586-7550; Web site: www.iscd.org.

Availability of Companion Documents

The following are available:

- 2013 official positions of the International Society for Clinical Densitometry. 2013 Aug. 16 p. Electronic copies: Available from the International Society for Clinical Densitometry (ISCD) Web site. Chinese and Indonesian translations of the official positions are also available from the ISCD Web site.
- Vertebral fracture recognition course. Available from the ISCD Web site.

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on July 27, 2009. The information was verified by the guideline developer on September 15, 2009. This summary was updated by ECRI Institute on August 21, 2014. The updated information was verified by the guideline developer on September 30, 2014.

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